MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

DATE: May 12, 1998
2550

FROM: Earl S. Dye, Ph.D., DARP

TO: License Number 1244

SUBJECT: Novartis Summary Basis of Approval

BLA: 97-1251

Manufacturer: Novartis Pharmaceutical Corportation
59 Route 10
East Hanover, NJ 07936-1080

Drug License Name: Basiliximab

Drug Trade Name: Simulect

Indications and Usage
Simulect (Basiliximab) is indicated for the prophylaxis of acute organ rejection in patients receiving renal transplantation when used as part of an immunosuppressive regimen that includes cyclosporine and corticosteroids.

Dosage Form, Route of Administration, and Recommended Dosage
Basiliximab is supplied as a lyophilized powder in single-use vial containing 20 mg Basiliximab, 7.21 mg monobasic potassium phosphate, 0.99 mg disodium hydrogen phosphate (anhydrous), 1.61 mg sodium chloride, 20 mg sucrose, 80 mg mannitol and 40 mg glycine. Vials are reconstituted with 5 ml sterile water for injection, USP. There are no preservatives.

Basiliximab is used as part of an immunosuppressive regimen that includes cyclosporine and corticosteroids. Only physicians experienced in immunosuppression therapy and management of organ transplantation patients should prescribe Basiliximab. The physician responsible for Basiliximab administration should have complete information requisite for the follow-up of the patient. Patients receiving the drug should be managed in facilities equipped and staffed with adequate laboratory and supportive medical resources.

Basiliximab is for central or peripheral intravenous administration only. Reconstituted Basiliximab (20 mg in 5 ml) should be diluted to a volume of 50 ml with normal saline or dextrose 5% and

administered as an intravenous infusion over 20 to 30 minutes. The recommended dose in adult patients is two doses of 20 mg each. The first 20 mg dose should be given within 2 hours prior to transplantation surgery. The second 20 mg dose should be given 4 days after transplantation. For children and adolescents from 2 up to 15 years of age, the recommended regimen is two doses of 12 mg/m^2 each, up to a maximum of 20 mg/dose. The first dose should be given within 2 hours prior to transplantation surgery. The second dose should be given 4 days after transplantation.

Basis for Approval

The basis of approval of Basiliximab for prevention of acute organ rejection in patients receiving renal transplantation is contained in the following appended documentation:

1. Committee Memo/Miller: Recommend Approval
2. Review Memo/Miller: CMC Section of BLA (Product)
3. Review Memo/Essayan: Clinical Safety and Efficacy Section of BLA
4. Review Memo/Neeman: Statistical Analysis of Safety and Efficacy Data
5. Review Memo/Trapnell: Clinical Pharmacology Section of BLA
6. Review Memo/Black: Nonclinical Pharmacology/Toxicology Section of BLA
7. Committee Memo/Miller: Administrative Decision History on Orphan Drug Issues
8. Review Memo/Hasemann: BiMo Inspection Summary
9. Review Memo/Brown: CMC Section of BLA (Facility)